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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,743	07/15/2003	Akira Yamada	240123US0DIV	7248
22850	7590	05/13/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			CHANG, CELIA C	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	
			1625	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,743

Applicant(s)

YAMADA ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1625

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 2-7, X is N, R3-R4 is ethylene i.e. piperazine compounds in the reply filed on Mar. 1, 2005 is acknowledged. The traversal is on the ground that the Examiner has not established independence and distinctness or burden in search wherein restriction is justified. This is not found persuasive because the instant case is a divisional of the issued parent case. Please note that the X is CH, as piperidine compounds have been issued as US patent 6,710,043 and propriety for restriction under PCT Rules 13.1 and 13.3 Annex B(A)(B)(1) and (B)(2) was clearly established in the parent case. An argument of nondistinctness *after* received some claims by applicants is self conflicting. The same restriction continuous of the prosecution history in selecting a different group supported by a single disclosed species is proper. Applicants provided no factual evidence to show that all species are obvious variation of each other or clearly admit such is the case in the record even though clear advice was made in the restriction office action.

The requirement is still deemed proper and is therefore made FINAL.

Based on the election, the scope of election and examination is the core structure for R3-N-E-X-R4 is a piperazine i. e. X is N, E is ethylene, R3-R4 forms ethylene, a non-condensed, unsubstituted piperazine ring.

2. Claims 1, 8, 9, 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The proviso conditions of the claims are very confusing. It is unclear what is provisoed out and what is within the scope. The examination is therefore, directed to the "elected" scope as delineated supra. It is recommended that the central ring be clearly drawn out for the elected scope.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1625

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by:

Matsuno et al. CA 131 :271888, see RN 245449-93-8;

Halazy et al. CA 127 :220673 see RN 194943-84-5, 194943-53-8;

Oku et al. CA 122 :187622 see RN 161683-16-5 ;

Gante et al. CA 123 :55917 see RN 164785-04-0 ;

Karimian et al. CA 121 :157669 see RN 157459-54-6 ;

Oshida et al. CA 116 :21062 see RN 138006-92-5 ;

Rajappa et al. CA 105 :208808 see RN 105288-89-4, 105168-70-5 ;

Vlattas et al. CA 96 :162759, see RN 81382-66-3, 81382-67-4;

Cain et al. CA 87 :62371, see RN 63178-64-3;

Yung et al. CA 87 :134271, see RN 64268-82-2, 64268-83-3, 64268-84-4 ;

Howell et al. CA 74:141902, see RN 31879-61-5;

Dahlbom et al. CA 57 :62765, see RN 93149-81-6.

Please note that the specification did not provide any definition of scope for the claimed terminology i.e. alkyl is C1-4 straight or branched carbon chain, only explanation of the terms “may be” embracing some exemplified moieties (see pages 9-25). Therefore, the terms must be interpreted broadly to include all substituted alkyl, aryl, cycloalkyl or heterocyclic group etc. as required by MPEP §2111. Anticipation was found with the above structurally delineated compounds and since the compounds are active pharmaceuticals, anticipation also applies to the composition claim.

Art Unit: 1625

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 98/27930 (cited on 1449).

See treating schizophrenia (abstract and p.9 claim 5) with example 1 (p. 7, line 30).

Claims 1-9, 11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Marston et al. US 6,284,760.

See treating schizophrenia (abstract and col. 5 line 18) with example 1 (col. 5, line 11 or col. 7-8, claims 26-27).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1625

Claims 1-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/27930 alone or in view of WO 97/28141 (cited on 1449) or US 5,708,172.

Determination of the scope and content of the prior art (MPEP §2141.01)

WO 98/27930 disclosed anticipatory compound useful in treating schizophrenia which has been clearly delineated supra and hereby incorporated by reference. Broadly, WO 98/27930 provided teaching on analogous variation of the exemplified compounds having analogous CNS activity (see p.2-3).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the WO 98/27930 reference is that not all the compounds within the class as taught on pages 2-3 were exemplified. Oku et al '172. taught that similar compounds with different linkage and substituents would not change the CNS activity of such piperazine core compounds (see whole article). Halazy et al. OW 97/28141 taught that more variation on linker and substituents to the piperazine core would offer good and effective treatment for schizophrenia (see abst, p. 1 line 25 and examples of compounds).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above reference placed CNS active piperazine compounds for treating schizophrenia in the possession of artisan in the field. Not only the references guided one skilled in the art to pick and choose variations of linkers and substituents, but also taught one skilled in the art of the modification in linker and substituents without compromising the CNS activity of the core. Therefore, one having ordinary skill in possession of the above references would be in possession of the instant claims because the active species has been exemplified and enable with guidance to linker and substituent modification to maintain CNS activity. In absence of unexpected result, the mere picking and choosing among the many analogous compounds with suggestions of modification to maintain functional activity is prima facie obvious.

6. Claims 1-9, 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-10 of U. S. 6,344,358 or claims 1-31 of U.S. Patent No. 6,284,760. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims fully embraced the copending claims. The issued claims are drawn to Y is NR5 compounds i.e. subgenus, while the instant claims fully embraced the issued claims.

Claims 1-9, 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim claims 1-6, 9-10 of U. S. 6,344,358 (cited on 1449) or claims 1-31 of U.S. Patent No. 6,284,760 in view of WO 97/28141 or US 5,708,172.

Art Unit: 1625

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Determination of the scope and content of the prior art (MPEP §2141.01)

Claims 1-6, 9-10 of US 6,344,358 or claims 1-31 of US 6,284,760 both commonly owned claimed using anticipatory compound for treating schizophrenia. Compounds of the issued patent are Y is NR5 subgenus of the instant claims.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and issued claims is that the instant claims embraced the issued compound as well as a broader scope wherein additional the linker and substituents other than NR5 were included. Oku et al '172. taught that similar compounds with different linkage and substituents would not change the CNS activity of such piperazine core compounds (see whole article): Halazy et al. OW 97/28141 taught that a broad variation on linker and substituents to the piperazine core would offer good and effective treatment for schizophrenia (see abst, p. 1 line 25 and examples of compounds).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above reference placed CNS active piperazine compounds for treating schizophrenia in the possession of artisan in the field. Not only the references guided one skilled in the art to pick and choose variations of linkers and substitutents, but also taught one skilled in the art of the modification in linker and substitutents without compromising the CNS activity of the core. Therefore, one having ordinary skill in possession of the above references would be in possession of the instant claims because the active species has been exemplified and enable with guidance to linker and substituent modification to maintain CNS activity. In absence of unexpected result, the mere picking and choosing among the many analogous compounds with suggestions of modification to maintain functional activity is prima facie obvious.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1625

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

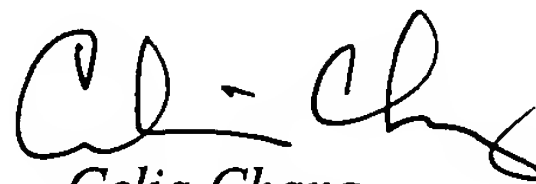
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 11, 2005


Celia Chang
Primary Examiner
Art Unit 1625